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Arkansas State Board of Pharmacy

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Attorney General Opinion 2008-166

The Arkansas State Board of Pharmacy requested an Attorney General's Opinion from Arkansas Attorney General Dustin McDaniel asking whether or not doctors of oriental medicine had the authority to prescribe, possess, and/or administer prescription legend drugs in Arkansas. The Attorney General's Opinion was released on December 12, 2008. The abstract for this opinion is below. To read this opinion in its entirety, you may go to the following link *www.arkansasag.gov/opinions/* and enter 2008-166 into the box beside the field "Retrieve an opinion by number." If you do not include both forward slashes on the Web site address it will not pull up, and if you do not include the dash in the opinion number it will not pull up the opinion. You may also view this opinion directly at *http://ag.arkansas.gov/opinions/docs/2008-166.pdf* or you can perform an Internet search of "Arkansas Attorney General's Opinion 2008-166" to find it as well.

Abstract for Arkansas Attorney General Opinion 2008-166

Q1. Does the definition of "related techniques" in A.C.A. 17-202-102(6) or any other section of the Arkansas Acupuncture Practice Act ("Act") authorize licensees of the Arkansas State Board of Acupuncture and Related Techniques ("Board") to prescribe legend drugs for their patients?

Q2. If licensees of the Board do not have authority under Arkansas law to prescribe legend drugs for their patients, do the provisions of A.C.A. 17-92-101 (16)(A)(i)(a), 20-64-506(a) and Board of Pharmacy Regulation 08-00-0004 also prohibit Board licensees from wholesale purchases of legend drugs for in-office use?

Q3. Does the "Scope of Practice" described in Title I(B) of the Rules and Regulations of the Board authorize Board licensees to prescribe or purchase legend drugs?

Q4. If the Act does not expressly authorize its licensees to prescribe or purchase legend drugs, may the Board promulgate a rule authorizing or permitting its licensees to prescribe or purchase legend drugs?

Q5. If licensees of the Board do have authority under Arkansas law to prescribe legend drugs for patients and for in-office administration, are they also authorized to prescribe controlled substances, as defined by Arkansas Uniform Controlled Substances Act, A.C.A. 5-64-101, et seq., and federal law Title 21 U.S.C. Sec. 800, et seq., Title 21 C.F.R. Part 1300, et seq.?

Response: In response to your first question, in my opinion, the Act probably does not authorize licensees of the Arkansas State Board of Acupuncture and Related Techniques (licensees) to prescribe legend drugs for their patients. In response to your second question, I do not believe that the provisions cited apply directly to licensees. In response to your third question, it appears that the cited regulations purport to authorize licensees to prescribe and/or administer certain listed types of medication, regardless of whether those medications qualify as legend drugs. In response to your fourth question, it should first be noted that whether the Act expressly authorizes the activities described is not dispositive, as the legislature may properly delegate some authority to the board. However, based on the statutory language, it is my opinion that the Act probably does not contemplate either the ability to prescribe legend drugs or the ability to purchase legend drugs for in-office administration. For this reason, it is my opinion that the regulations which allow licensees to engage in such activities could be found ultra vires of the Act. In response to your fifth question, in light of my responses to questions one (1) and four (4), it is my opinion that licensees are not authorized to prescribe or administer controlled substances.

Technician and Business Permit Renewals

As a last reminder, the Arkansas State Board of Pharmacy sent out permit renewals for pharmacy technicians, charitable clinic pharmacies, institutional pharmacies, wholesale distributors, List 1 chemical distributors, hospital pharmacies, nursing home consultants, and durable medical equipment permits in October 2008. Charitable clinic permits and institutional permits cannot be renewed via the Internet but all others may be renewed through our Web site. It should be noted that if these permits were not renewed, they expired on December 31, 2008. The Arkansas State Board of Pharmacy allows a grace period until March 31 on permits. However, there is a $20 penalty on permit renewal if not renewed by February 1, a $40 penalty if not before March 1, and if a permit is not renewed by April 1 then the permit is void. This means that in order to get a technician permit again, an individual must apply for reinstatement and undergo a criminal background check that includes fingerprinting and payment of reinstatement fees. We would strongly encourage you to use our Web site to renew permits via the Internet as it will speed up the renewal process for you and it will also reduce the turn around time to receive a new permit. This is also the only way that we can accept credit card payments for renewal of these permits.

Arkansas Drug Information Center

The Arkansas Drug Information Center is a University of Arkansas for Medical Sciences (UAMS) College of Pharmacy service component that is available to Arkansas health care professionals. The center is open Monday through Friday from 8:30 AM to 5 PM. The primary function of the center is to receive and answer drug information questions of all types. To locate the needed information, the staff members and senior pharmacy students utilize the extensive print and online drug and medical information resources available in the center and in the UAMS Library, as well as other resources such as drug companies and Food and Drug Administration. The toll-free telephone number is 888/228-1233 and

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FDA Web Site Upgrades Support MedWatch's Patient Safety Goal

Two recently launched additions to the Food and Drug Administration's (FDA) Web site are intended to support the "Patient Safety" goal that MedWatch shares in public health efforts to protect patients from serious harm and improve outcomes. The entry pages assist health care professionals and patients to locate timely safety information for FDA-regulated human medical products and assist them in making diagnostic and therapeutic decisions.

The content and links on the new FDA entry page specifically for health care professionals allows busy doctors, pharmacists, nurses, and other health care professionals to find information to make point-of-care decisions. There is information that is specifically safety-related, such as easy access to reporting adverse events or finding new safety alerts, warnings, and recalls. Users can also find content regarding new approvals information, or access to the current version of the label, or prescribing information in "DailyMed." This page can be accessed through *www.fda.gov/healthprofessionals*.

FDA's other new page is specifically for patients and provides two patient-friendly articles about reporting adverse events and product quality problems to FDA and to the patient's caregivers. These articles are also available to pharmacists in printer-friendly PDF versions that can be downloaded and distributed to patients. FDA relies on properly and timely reporting of serious and unexpected drug and device-related adverse events, use errors, and quality problems. Pharmacists can ascertain and teach their patients to understand the "what, why, and how" to report to FDA and also learn about what happens to each received report and whether it leads to FDA action that may make product use safer for both patients and providers. FDA's patient specific page can be found at *www.fda.gov/consumer/default.htm*.

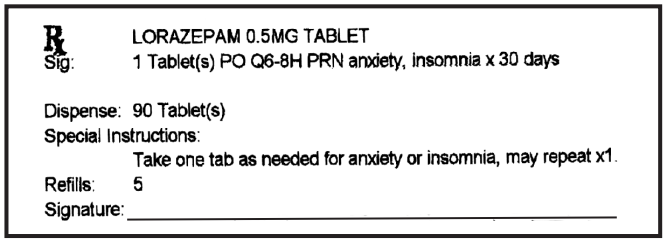
Retail Pharmacies Now Providing Medical Clinics to Improve Public Safety

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Retail pharmacy corporations have set up medical clinics within pharmacies. These nurse-practitioner or physician-assistant run clinics aim to rapidly diagnose and treat a limited number of health problems. Many also offer vaccination programs. The first pharmacy-based medical clinics were opened in Minnesota as QuickMedx in 2000, later becoming MinuteClinic in 2002. Currently there are approximately 1,000 sites in 37 states representing almost three million cumulative visits.

The emergence of pharmacy-based medical clinics offers a unique set of opportunities to improve the safety in prescribing and dispensing medications. Do you have a clinic opening in your store? If so, consider these safety recommendations:

- Meet the nurse practitioners and physician assistants and introduce them to your staff. Show them how your operation works and invite them in for a tour.
- If you have prescription scanning capabilities, show them how a scanned prescription displays on your monitor. Show them how different prescription blanks scan (eg, colored prescription blanks, blanks with water marks or seals for diversion) and what to avoid using so as not to distort the actual order.
- If they are using a device that allows them to send prescriptions electronically, have them send test prescriptions to you, invite them in to see how their prescriptions display on your computer and send them back test refill requests.
- Work together on any issues that arise, such as conflicting directions and special instructions, where the automatic sig indicates one set of patient directions and then the free text special instructions contradict the sig (see image below).



- Ask prescribers to include the indication for use whenever they write or call in a prescription.
- Educate them that it is your policy to read back the entire prescription order to them after transcribing it in the pharmacy including spelling the medication name. Let them know you will be using "cock-pit" language, for example, "one six" for "16."
- Ask them to include both the generic and brand names on all written orders for medications with look-alike and/or sound-alike names.
- Share with them ISMP safety tools (eg, List of Error Prone Abbreviations, List of Confused Drug Names) found at *www.ismp.org/Tools*.

- Let them know you will dispense measuring devices every time they order a liquid medication.
- Let them know that safety is your priority when filling prescriptions, and invite them to be part of your safety team.

FDA Launches Web Sites on Promotion of Medical Products

On September 3, 2008, FDA launched two new Web sites to provide information for consumers and industry about how FDA regulates the promotion of medical products. Pharmacists can obtain useful information regarding prescription drug advertising regulations as well as refer their patients who may have questions to the site.

The "Advertising Prescription Drugs and Medical Devices" Web site provides a "one-stop shop" portal to information on FDA regulation of medical product promotion. Pharmacists access relevant laws, regulations, and guidances. This site can be found at *www.fda.gov/oc/promotion/*.

The direct-to-consumer Web site, "Be Smart about Prescription Drug Advertising: A Guide for Consumers" is designed to educate consumers about how to view such advertising to help inform their discussions with health care providers, and consequently to help improve patient's understanding and medical care. This site was created in collaboration with EthicAd, an independent, nonprofit organization dedicated to helping consumers, health care professionals, and the pharmaceutical and advertising industries with direct-to-consumer advertising for prescription drugs. More information can be found at *www.ethicad.org*.

The direct-to-consumer site provides interactive example ads for fictitious drugs to illustrate the different requirements for the various types of ads. It also includes a list of questions patients should ask themselves when they see a prescription drug ad. This list can be printed for patients to use while discussing questions with their health care providers. This site can be found at *www.fda.gov/cder/ethicad/index.htm*.

FPGEE Returns to Computer-based Format

As advancements in secure testing technology forge ahead, the push for more electronically based systems and less use of the traditional paper-and-pencil mechanisms continues. With this in mind, NABP will soon be returning the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) to a computer-based format, eliminating the paper-and-pencil examination.

The FPGEE is the third computerized examination to be developed by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). The new computerized FPGEE will debut at the April 14, 2009 administration.

The computerized FPGEE examination will continue to be administered one day in the spring and one day in the fall; however, instead of limiting the available testing locations to three sites, applicants will be able to choose from more than 200 Pearson VUE testing sites located within the continental United States. In addition, it is anticipitated that applicants will be able to schedule their test sites electronically 48 to 72 hours after having been accepted to take the FPGEE.

The NABP test vendor, Pearson VUE, will administer the computerized FPGEE as it does with the NAPLEX and the MPJE. Demonstrating a record of solid customer service combined with a secure and consistent test center network, Pearson VUE is committed to providing a reliable and professional testing environment for applicants on behalf of NABP.

The FPGEE is one component of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification process. In addition to passing the examination, FPGEC applicants are required to have certain documents submitted from educational and licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants must also pass the Test of English as a Foreign Language ™ (TOEFL®) and the Test of Spoken English™ (TSE®), or the TOEFL Internet-based Test (iBT). The FPGEC certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Examination Programs section on the NABP Web site at *www.nabp.net*.

Updated 2009 Survey of Pharmacy Law Now Available

The NABP 2009 *Survey of Pharmacy Law*, providing a concise research source for key regulatory questions in pharmacy practice for all 50 states, the District of Columbia, and Puerto Rico, is now available.

The *Survey* updates, graciously provided by the state boards of pharmacy, consist of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Also, a new question in Section VII, "Issuance of Initial Pharmacist Licensure," asks whether or not states require criminal history record checks for initial licensure as a pharmacist.

To order the *Survey*, visit the NABP Web site at *www.nabp.net* and download an order form; the *Survey* costs $20.

All final-year pharmacy students receive the CD-ROM free of charge through the generous sponsorship of Purdue Pharma LP.

More information on the *Survey* is available by contacting customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Continued from page 1

the Little Rock local number is 686-5072. These phone numbers are not advertised to the general public, but pharmacists are welcome to provide the phone number to individual patients who have a drug information question (other than a medication identification question).

Medication identification (pill ID) questions: The Arkansas Drug Information Center and the Arkansas Poison Control Center (1-800/376-4766, available 24 hours per day) provide a medication identification service to Arkansas health care professionals, members of law enforcement, and school officials. If a member of the general public calls either center with a pill ID question, the caller will be informed that the center must receive such a request from a health care professional.

From DEA Diversion Control Q & A

Following a number of questions and the article from our last *Newsletters* the Board is including a copy of Drug Enforcement Administration's (DEA) Office of Diversion Control, General Questions and Answers. This list has been updated since our last *Newsletter* was sent for publication and comments from the Arkansas State Board of Pharmacy are included below.

Question: Is it permissible to dispense a prescription for a quantity less than the face amount prescribed resulting in the actual number of dispensings being greater than the number of refills indicated on the prescription?

Answer: Yes. Partial refills of Schedule III and IV controlled substance prescriptions are permissible under federal regulations provided that each partial filling is dispensed and recorded in the same manner as a refilling (ie, date refilled, amount dispensed, initials of dispensing pharmacist, etc.), the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed and no dispensing occurs after six months past the date of issue.

Question: What changes may a pharmacist make to a prescription written for a controlled substance in Schedules III through V?

Answer: The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions. The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

Question: What changes may a pharmacist make to a prescription written for a controlled substance in Schedule II?

Answer: On November 19, 2007, DEA published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [Schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the rule's preamble are in opposition to DEA's previous policy, which permitted the same changes a pharmacist may make to Schedules III through V controlled substance prescriptions after oral consultation with the prescriber. DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

Arkansas State Board of Pharmacy Reflection on the above statement and answer: The Arkansas State Board of Pharmacy continues to allow the changes to a Schedule II prescription as had been previously published in this *Newsletter* after consultation with the prescribing physician including: the pharmacist is permitted to add or change the dosage form, drug strength, drug quantity, directions for use, and issue date. The pharmacist is permitted to make information additions that are provided by the patient or bearer, such as the patient's address, and such additions should be verified. The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

Arkansas Pharmacy Support Group Help Line
870/636-0923

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